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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/160,076	09/24/98	SCOTT D	308072000110

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EXAMINER	
WILSON, M	
ART UNIT	**PAPER NUMBER**
1633	14

DATE MAILED: 05/30/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action

Application No.	Applicant(s)
09/160,076	Scott et al.
Examiner	**Group Art Unit**
Wilson, Michael C.	1633

THE PERIOD FOR RESPONSE: [check only a) or b)]

a) ☒ expires 6 months from the mailing date of the final rejection.

b) ☐ expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☐ Appellant's Brief is due two months from the date of the Notice of Appeal filed on _____ (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

Applicant's response to the final rejection, filed on May 9, 2000 has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:

☒ The proposed amendment(s):

☐ will be entered upon filing of a Notice of Appeal and an Appeal Brief.

☒ will not be entered because:

☒ they raise new issues that would require further consideration and/or search. (See note below).

☐ they raise the issue of new matter. (See note below).

☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: *claims 52-54 raise a new 112/2nd rejection in the phrase "wherein said fusion immunoglobulin comprises..." because it is unclear how a variable region comprises an antigen epitope as claimed. (see also below)*

☐ Applicant's response has overcome the following rejection(s):

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SUPERVISORY PATENT EXAMINER
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☐ Newly proposed or amended claims _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claims.

☒ The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See attached paper.

☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

☒ For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):

Claims allowed: _____

Claims objected to: _____

Claims rejected: *31-51*

☐ The proposed drawing correction filed on _____ ☐has ☐has not been approved by the Examiner.

☐ Note the attached Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ .

☒ Other *Claims 52-54 reqiure a new search - the new step of inducing immunological tolerance was not required in the body of the previous claims. Claim 34 is indefinite because of the term "mediates". Applicants proposed amendment would overcome the 112/2nd regarding "functional" and "associated with" upon entering. Applicants arguements are discussed on the attached paper.*

Applicants argue the nucleic acid sequence of antigen E of ragweed as well as other sequence in GenBank were known in the art and cited on page 10; therefore, applicants argue the burden of written description has been met. Applicants provide a list of antigens which were known in the art at the time of filing in Exhibit A. An adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself. The DNA sequences listed in Exhibit A are not described in the specification. Therefore, the specification lacks written description for any antigen of pollen, ragweed or dust mite as claimed.

Applicants argue the claims are enabled because 5 examples in which vectors are made used to obtain immunological unresponsiveness. The pending claims are not enabled as broadly written because the specification does not teach any tolerogenic epitopes of any proteins. The specification does not teach any antigens of pollen, ragweed or dust mites, provide the nucleic acid sequence of such allergens or teach any tolerogenic epitopes derived from pollen, ragweed or dust mites as claimed. It would require one of skill to determine the tolerogenic epitopes of the exceedingly numerous proteins found in any protein. The specification does not provide adequate guidance to transform cells with a vector encoding epitopes from pollen, ragweed, dust mites, clotting factor VIII, acetylcholine receptors, collagen, myelin basic protein, thyroglobulin, and histocompatibility antigen such that the epitopes are tolerogenic as claimed.

Applicants proposed claims have not been entered; therefore, all of the 112/2nd rejections remain. Applicants argue that the term "autoantigen" is definite because the term is defined as

"self-antigen" and any tissue constituent that evokes an immune response. Applicants argument is not persuasive. The term is confusing because applicants invention is attempting to prevent an immune response while the definition states autoantigens evoke an immune response. The term is also relative because the immune system may recognize self-antigens during development to induce tolerance but eventually does not respond to self-antigens under normal conditions. In addition, the term "autoantigen" is used in relation to a person which is not recited in the claim. For example, the melanoma antigen MART-1 is an autoantigen in every melanoma patient. Therefore, the metes and bounds of antigens which are "autoantigens" cannot be determined.

Applicants argue the claims are being interpreted too broadly. Applicants argument is not persuasive. Given the teachings in the specification taken with the indefiniteness of the claims and the teachings in the art, the broad interpretation of the claims is proper. Applicants provide arguments regarding proposed limitations which are moot because the proposed amendment has not been entered. Therefore, the pending claims remain rejected under 102 and 103 for reasons of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson whose telephone number is (703) 305-0120. The examiner can normally be reached on Monday through Friday from 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. The fax phone number for this Group is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 305-0196.

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